EXHIBIT C

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS
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In re: NEURONTIN MARKETING,SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION MDL Docket No. 1629
----------x No. 04-10981
THIS DOCUMENT RELATES TO:
PRODUCTS LIABILITY LITIGATION
----------x
SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK
----------x
IN RE: NEW YORK NEURONTIN PRODUCTS LIABILITY LITIGATION
----------x
THIS DOCUMENT APPLIES TO:
ALL CASES
----------x CONTAINS CONFIDENTAIL INFORMATION

The Videotaped deposition of SHEILA WEISS SMITH, PhD., was held on Wednesday, January 9, 2008, commencing at 9:12 a.m., at the Law Offices of Goodell, DeVries, Leech & Dann, LLP, One South Street, Baltimore, Maryland, before Ronald E. Bennett, Notary Public.
Reported By: Ronald E. Bennett

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Deposition of SHEILA WEISS SMITH, Ph.D.

January 9, 2008

EXHIBITS

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(Deposition Exhibits Number 1-5 marked for purposes of identification.)

Whereupon,

SHEILA WEISS SMITH, Ph.D.,

called as a witness, having been first duly sworn to tell the truth, the whole truth, and nothing but the truth, was examined and testified as follows:

EXAMINATION BY COUNSEL FOR PLAINTIFF
BY MR. FROMSON:

Q. Is it Dr. Weiss? Dr. Weiss-Smith or Dr. Smith? How would you like to be addressed this morning?

A. It's Dr. Weiss-Smith.

Q. Thank you. Dr. Weiss-Smith, good-morning.

A. Good morning.

Q. My name is Ken Fromson. I'm going to ask you a series of questions involving the report that you have provided on behalf of defendants in this case, the drug companies, Park-Davis, Warner-Lambert and Pfizer. Do you understand that?

A. Yes, I do.

Q. And I would ask, if you could, this morning to keep your voice up so that we can make sure that the court reporter can understand what you

Q. Are you aware that the language you quote is not found at page 526 of that edition?
A. I do not quote any --
Q. I'm sorry. Let me rephrase the question. Are you aware that the language you quote and reference -- are you aware that the language you referenced being at page 528 and 529 is not at 528 and 529?
MR. BARNES: Please look for the text of this and find the citations.
MR. FROMSON: I withdraw the question. Withdrawn. I'll ask it the way I want to ask it, Rick.
MR. BARNES: That's fine.
BY MR. FROMSON:
Q. Let's get to the point of the matter. Your references are wrong at certain parts of your report. The quotes in fact may be in the electronic version. Is that basically your position?
A. One, there are a few quotes. And yes, I would stand by what I wrote. Now if I reference something, it doesn't mean that I'm quoting it.
Q. When you reference something and you reference it to a page number, you expect the reader to be able to go to that page number and find the

reference. Would you agree with that?
A. Absolutely.
Q. And in this case you would agree in fact that the reference to page 528 and 529 of the second edition, the paper edition, that reference is not at page 528 and 529?
A. I apologize for the error. I wish I had someone editing it with that accuracy so I would have found that beforehand. I apologize.
Q. Thank you. At page 26 of your paper, Doctor, you cite to Vilhjalmsson, doctors associated with suicide ideation in adults with a reference date of 1998. Do you see that citation?
A. Yes, I do.
Q. Would you be surprised to know that the language you quoted is not found in that article?
A. I don't quote anything there.
Q. Do you not in fact have this language in quotations at page 26, immediately preceding the Vilhjalmsson cite. You state, "Reports that document positive rechallence do not prove a causal relationship for events such as depression that have a high background rate and a chronic remitting natural history."
Did I read that sentence correctly

from your report?
A. No. It talks about the FDA scientist O'Connell, Witkin and Pitts.
Q. So in fact, you want me to read the whole sentence. Doctor, tell me if I'm reading this correctly from your report. Particular to depression, FDA scientists Drs. O'Connell, Wilkin and Pitts write that "Reports that document positive rechallence do not prove a causal relationship for events such as depression that have a high background rate and a chronic limiting natural history."
Doctor, did I read that correctly?
A. That is what I wrote.
Q. You cite to Vilhjalmsson in an article from 1998 immediately after the quote. Am I correct?
A. Yes, there is that citation afterwards.
Q. That citation is incorrect, isn't that true?
A. I don't know. I would have to look at it.
MR. FROMSON: I'll mark for Exhibit 6 a copy.
(Deposition Exhibit Number 6 marked for purposes of identification.)

BY MR. FROMSON:
Q. You now have Exhibit 6 in front of you, Doctor?
A. Yes, I have Exhibit 6.
Q. Is that in fact the Vilhjalmsson article from 1998?
A. Yes, that is.
Q. The language that you quote that immediately preceded the cite, is that language that you quote in the Vilhjalmsson article, now that the article is in front of you?
A. The quotation for Vilhjalmsson goes toward the high rate of suicide and chronic remitting natural history. So the issue, why I'm quoting Vilhjalmsson or not quoting but citing him is the last part of the sentence. He's writing about factors associated with suicide ideation in adults.
Q. Let me see if I understand you here. You're saying, as an experienced author of peer reviewed journal articles, that when you include a sentence with a quote, that immediately following the quote you can cite to a different reference for the quote itself?
A. Each journal cites differently. Now if I was citing for a journal where I would have a

little, what you call it, one of those little superscripts, I would have put the superscript right after natural history.

Now you guys seem to do it differently. But the issue is, Vilhjalmsson talks about factors associated with suicide ideation. I'm trying to reference the fact that it has, depression has a high background rate in remitting chronic history.

So the issue is, that you can't separate the reason people are getting the drug from the outcome that we are talking about here. I'm just saying that's why he's cited for that part, as backup for what they say in their quote.

Q. Your position is, the citation is accurate?

A. Yes.

Q. And Wilkin and Pitts are nowhere in the Vilhjalmsson article. You cite them that they were in some other source.

A. I cite them before. Exactly. I cite them earlier.

Q. You don't cite where they write it. Presumably they write it somewhere and the quote is accurate as to Wilkin and Pitts and O'Connell,

right?

A. Yes.

Q. You believe that the readers of this report should have understood the manner that you put forth this cite?

A. I would hope so. Yes.

Q. And you felt it was important and meaningful to include the citation from Vilhjalmsson related to his reference to suicidal ideation, right?

A. Yes. In that it talks about depression.

Q. You felt that because it talked about depression it was meaningful for your report?

A. For this issue, yes.

Q. You don't list for the reader the actual source for the writing of Wilkin, Pitts and O'Connell though in the text?

A. I apologize. I probably should.

Q. That's a mistake. That was a mistake?

A. An oversight.

Q. It was an oversight. Is it an oversight you just learned from me, despite the fact that you reviewed this?

A. Yes, I didn't realize I didn't put that citation in. Might be in earlier.

MR. BARNES: You want to review and see if it's cited earlier in the report? That would be just -- just saying to respond to your question.

MR. FROMSON: I appreciate the coaching, Counsel.

MR. BARNES: You asked her --

MR. FROMSON: I asked her if her cite is there. It's not there. Let me move on.

A. It's not at this paragraph --

BY MR. FROMSON:

Q. Could be somewhere else in the report.

On page 27, Doctor, you use the term in the end of the first full paragraph uninterruptible. Can you tell me what that means?

A. That is Bill Gates working. Uninterpretable.

Q. So you did a spell check and when it did it, it changed to uninterpretable to uninterruptible?

A. Unfortunately it just changes it automatically, yes. Uninterpretable.

Q. At page 5 of your report again you cite to the Reference Manual on Science Evidence at page 90 and 91. Specifically you say that, case reports cannot be used to establish an association, because

they lack a control or comparison group; they are merely reports occurrences of an outcome. Am I correct?

A. Which paragraph are you on?

Q. It's the first full paragraph. It's actually the second paragraph beginning with the words case reports.

A. Yes.

Q. When you reference case reports in this context, are you referring to spontaneously reported post marketing adverse event case reports or are you referring to case reports from clinical trials, both or something else?

A. Case reports. Clinical trials are not considered case reports. So case reports could be from public literature or could be given to the FDA through spontaneous reporting. I'm not differentiating the source of the report. Just a report of a event.

Q. If a case report in this context or in any context the reference to case report in your mind is not referring to clinical trial. How do you label an individual case in the clinical trial? What should we call it for purposes of today's deposition?

A. People use the same technology. Just having a case in isolation, even if it's in the clinical trial, is itself not a statistical association. Unless you have a comparator group. So yes, you can have a case, an event from a clinical trial. In fact, that's what you have from the average report. They are individual cases.

Q. I think we are on the same page. So then, when you reference case reports in this text that, the proposition that they cannot be used to establish an association for the reasons listed, would be the same whether it's in a clinical trial or a spontaneously reported post marketing adverse --

MR. BARNES: Objection.

Q. Would that be true or not?

A. In the clinical trial it's a different issue. Because you have a randomized control group. So this is a very odd question. It makes no sense.

Q. I appreciate that. I really do. I want to make sure I try to make sense here.

Would a case from a clinical trial where you may have a control group, would that be a situation where you could establish an association then?

article, it was published in British Medical Journal that talks about these very unique adverse events. But in general that wouldn't be an issue.

MR. BARNES: Is it time for a break?

THE WITNESS: I think that would be a great idea. Thank you.

(Brief Recess.)

BY MR. FROMSON:

Q. Doctor, would you turn to page 26 of your report. Referencing your attention to our earlier discussion regarding FDA scientists Dr. O'Connell, Wilkin and Pitts and what they write as you reference in your report. Could you please identify for me in your materials list, which are Exhibits 3 and 4, where you reference the source for Drs. O'Connell, Wilkin and Pitts?

A. I believe it is the meeting at the FDA. So it's somewhere in these --

MR. BARNES: One of these internet sites.

Q. Which internet site is it, Doctor, so that the layperson who is reading your report would know which source it was?

MR. BARNES: Can she check the internet just to verify.

A. I would want to verify that I can --

A. I can't answer it in that context. It just doesn't make sense what you are asking.

Q. What if I were to replace the words case reports in your report, which basically refers to, you're referring to postmarking adverse events there, if I were to replace it with case reports from clinical trials, would that make the question make sense or no?

MR. BARNES: Objection. You may answer.

THE WITNESS: What do you mean when you are asking me a case report from a clinical trial?

Q. Okay. A report of an adverse event or untoward event that was observed by an investigator during a clinical trial of a participant or patient which was observed during the ingestion period of drug in question?

A. A single event that occurs in isolation is uninterpretable in isolation in this context. However, that's not how clinical trial is designed to work. So it's a little different.

Q. Can a single case in a clinical trial ever establish an association?

A. Hypothetically, in some very unique circumstances potentially. Like I said, extremely rare hypothetical. I think Dr. Hauben wrote an

Q. At the time you request the next break we can maybe check that.

So you believe it was written or now do you believe it was stated, because if it was at a meeting, it would have been stated.

A. It would have been part of the briefing materials. It might be this one. We'll have to check, from the FDA advisory committee.

Q. That would have been involving isotretinoin or Accutane?

A. I don't know -- I know what was -- Cheryl Blume had quoted that. I don't know if it was that one or the other. So I'll have to double-check it. But it was definitely one of the internet sites. I'll have to find out exactly which one.

Q. I'll see if I can assist and expedite the matter, notwithstanding the fact that you may have seen it with internet site, I'll submit to you that the quotation is in the Journal of American Academy of Dermatology, February 2003. We can have that marked as Exhibit 6.

MR. BARNES: Exhibit 7.

(Deposition Exhibit Number 7 marked for purposes of identification.)

BY MR. FROMSON:

Q. Do you have what's been marked as Exhibit 7. Do you have the exhibit?
A. Yes, I have the exhibit. Thank you.
Q. Can you turn to page 2 of the exhibit, the third full paragraph beginning with the word reports. Do you see the word reports?
A. Yes, I do.
Q. Would that quote be consistent with the quote that you have in your actual report?
A. It's not identical.
Q. It's not identical?
A. No.
Q. Okay.
A. I don't believe I quoted this article.
Q. Let's see if we can read it together. Your report says at page 26 --
A. I see. I was looking at the second one.
MR. BARNES: Let her catch up to you.
MR. FROMSON: Sure.
Q. It's not a trick question, Doctor. The quote from the Dermatology Journal starting with the word reports.
A. I apologize. I was looking at the next sentence, which was not verbatim. This is. I reviewed it now.

Q. Can we agree that the quote in the journal article, which is marked as Exhibit 7, is quoted in your report at page 26?
A. Yes, that's the same words.
Q. The words are, reports that document positive rechallenge do not prove a causal relationship for events such as depression that have a high background rate and a chronic remitting natural history, correct?
A. Yes.
Q. You did not include in your expert report the very next sentence, which in fact states, nonetheless, positive rechallenges are very important evidence in overall causality assessment of isotretinoin and psychiatric adverse events.
You didn't include that specific quote with that specific language, correct?
A. No, I did not.
Q. And you understand that these writers, these scientists, O'Connell, Wilkin and Pitts, were making these statements in the context of isotretinoin, otherwise known as Accutane, correct? The word isotretinoin is in the quote, Doctor?
A. I'm looking for the signatures. Yes.
Q. Isotretinoin was a drug which the FDA was

evaluating for depression and suicidality, correct?
A. I have heard that they were doing that, yes.
Q. You are actually on a science advisory board --
A. -- advisory board.
Q. For Accutane, correct?
A. For the pregnancy registry, yes.
Q. Your experience with the science board has nothing to do with the suicidality assessment for Accutane. Would that be fair?
A. That is correct.
Q. Now, would you agree with the general premise, as stated by these scientists O'Connell Wilkin and Pitts, and as quoted in the journal article, that positive rechallenges are very important evidence in overall causality assessment and psychiatric adverse events?
A. I agree with the first sentence of that paragraph. However, the scientifically, I would disagree that they provide good evidence. So, in other words, the science I agree with in the first sentence.
The second sentence they are stating what they used. And I have -- I don't necessarily

agree that that is a good use of such. And it actually contradicts their earlier sentence.
Q. Let me see if I can be on the same page with you. Is it that you don't believe positive rechallenges are evidence of causality or that you don't believe positive rechallenges are very important evidence in overall causality assessment. Or is it something else?
A. Well, you're taking this sentence out of context. They are saying in a very specific circumstance, of which I don't have the entire dossier, that they were important in their overall causality of this issue.
I would have to review that issue in total. So I don't know the context of that. I agree with the first sentence. This is a generally accepted principle that the positive rechallenges are not good evidence for events such as depression.
Q. So when you quoted this for the proposition that was favorable essentially to the defendant's case, you were aware that O'Connell, Wilkin and Pitts were rendering their statement in the context of Accutane, correct?
MR. BARNES: Objection. I'm not sure you laid a foundation for, if she has seen this before.

This is what she actually saw.
BY MR. FROMSON:
Q. Fair enough. When you saw or recognized or observed their statements that you did believe it, which you quoted in the report, you either got it from a journal article or you got it from the FDA's copy of the hearing transcript.
A. They actually had a little summary posted on the website.
Q. The summary posted on the website would have been for the Accutane meeting that took place at the time?
A. Yes, it would have related to that.
Q. So again, I'm not trying to ask you a difficult question. You would have known, when you relied or considered that source, that the source was being given in the context of Accutane?
A. The statement, the very first statement that reports a document positive rechallenge do not prove a causal relationship events such as depression that have a high background rate in chronic history is a generally accepted principle in the field.
And I quote it because I want to make sure that that is very clear, the scientific context

that we are discussing in this case. How they use them professionally in one case or another I may have a difference of opinion with.
Q. So you are basically using the language that was provided as a general statement but within the context of an Accutane hearing and you are applying it in the context of the Neurontin litigation?
MR. BARNES: Objection. Go ahead. You may answer.
A. I'm taking the principle, the scientific principle, which they clearly state, and putting that, because it is a similar issue, putting that in context, yes.
Q. What, if anything, prevented you from including the second sentence, the one you don't agree with, and indicating to the layperson who is reading the document that the second sentence was also said in the context of Accutane and it's not applicable here?
A. Because it has nothing to do with this case. No sense to put it in.
Q. You believe that that opinion that you just gave, that statement that you just gave, would be consistent with scientifically sound methodology

in submitting fair and accurate information?
A. Yes.
Q. You have no understanding as to why the second sentence, the one that you don't agree with, was important to the FDA scientists, Pitt, O'Connell and Wilkin, right?
A. You're putting words in my mouth. I'm not saying I agree or disagree. That second sentence is a statement of fact that they took these into account in their causal assessment. It's not a scientific opinion.
Q. Maybe I wasn't clear. Do you have any reason to disagree that positive rechallenges were very important evidence in the overall causality assessment of Accutane in psychiatric adverse events?
A. I have no reason to state any opinion because I did not read that full report on the causality, in their causality assessment.
Q. Why didn't you read the full causality assessment to see if there were any analogies that can be made to the Neurontin litigation, particularly since they were a lymphatic drug and an association with suicidality. And you're looking at a drug that had a potential for association with

suicidality?
A. Because I reviewed the literature for this specific drug. If I looked at the literature for every drug and every suicide, I would need probably five years to do this case. And I didn't have that.
Q. Why not look at drugs that have a similar pharmacologic action?
A. If there were any signal at all, I may have expanded my search. But there was absolutely nothing to reasonably rationally do that. There was absolutely nothing in the evidence for this drug.
Q. With respect to the first sentence in the O'Connell letter or as it was reflected in the hearing or meeting transcript you read, in any way shape or form the fact that you quote in your report, does that statement mean to you that it was generally accepted in the community?
In other words, does that statement reports the document positive rechallenge not prove a causal relationship for events such as depression that have a high background rate and a chronic remitting natural history. Is that generally accepted?
A. I believe so. That it is a standard in pharmacovigilance.

A. Again, the seriousness or non-seriousness is based on the patient outcome, not on event term.
Q. I understand that. But basically did you look to see whether there were serious suicidal ideations in the system?
A. Again, that would have to be a clinical judgment, because there would probably be more terms in the report. And for me to make a judgment of which term was related to the outcome would be inappropriate.
Q. Instead of asking them individually, I'll run through them. There is not that many. Intentional self-injury, suicidal ideation, self-injurious ideation, self-injurious behavior, self-mutilation and suicidal behavior.
My first question as to those terms, were you aware those are terms in the adverse event database?
A. I believe I've seen them in the MedDRA dictionary.
Q. Are you aware that those are in fact adverse events that have been reported on a serious basis in the adverse event database?
A. On a serious basis?
Q. They are marked as serious, they are

reported as serious adverse events?
MR. BARNES: Objection.
A. That would be speculation for me to link the outcome with the event.
Q. Would you look at the report to see what that person thought it was? The outcome of the patient you said is what determines whether it's a serious adverse event, right?
A. I did not do a clinical evaluation of individual reports.
Q. Did you inquire of the defendant as to whether you should?
A. I'm not a clinician. I had no -- it's beyond my purview. I wouldn't presume to make a clinical evaluation report.
Q. I understand that you don't, you in your field, don't make a determination of whether an adverse event is serious or not serious. Because you are not a clinician, correct?
A. That's correct.
Q. But there are reports in the adverse event database that are available to you which are not suicide and suicide attempt, but are any of the other ones I referenced to you, and which are in fact serious, requiring no clinical judgment on your

part, they are marked as serious or non-serious in the adverse event database. Do you agree with that?
MR. BARNES: Objection. Asked and answered. You may answer again.
A. I did not go and investigate this issue. And, again, you are mixing up adverse event terms with patient outcomes. And they are two different things.
Q. These terms are contained in the reports where the overall report is marked as serious. That's what I'm telling you. You simply don't know because you didn't look, right?
A. There's two issues; one, I didn't go and pull these terms. And two, just because a term exists on a report does not mean that that is the reason for being marked serious or non-serious. There may be other events mentioned also.
Q. But you're not supposed to evaluate that. You're not a clinician. You are just supposed to, as a mathematical expert in epidemiology, you are supposed to go, let me look at serious adverse events. And I'm going to -- you're supposed to look at the serious adverse event reports, cull them and do an analysis of them. You chose to limit it to suicide and suicide attempt for the reasons we have

already discussed today?
A. I limited it because these are reasonably defined outcomes and, for example, suicide in itself is always a serious event, whether or not the check box would be checked for that.
Q. You think self-mutilation is a serious event?
A. I have no opinion on that.
Q. And you are not aware whether it's in the adverse event database as a serious event report, because you didn't look?
A. Absolutely.
Q. Suicidal behavior. You have no opinion, you have no clinical opinion as to whether that's a serious event, correct?
A. I have no opinion about the clinical.
Q. You are not aware of whether any suicidal behavior adverse event reports were marked as serious, because you didn't look for that, right?
A. I don't want to blanket because some of the events that you're saying, even a layperson knows that they may be non-serious.
Q. They will be marked as such, won't they? If they are in the adverse event reporting system, won't they be marked as serious or non-serious?

There were a number of suicides, very, very small. I think by 1999 there were a handful.

Q. I don't want to know about '99. I want to know between '93 and '97 you indicated that there were zero completed suicides -- I'm sorry -- you indicated the PRR was zero from '93 to '97 for completed suicides.

A. That is correct.

Q. And that would have been utilizing the Costart dictionary?

MR. BARNES: Objection.

A. That is incorrect.

Q. What dictionary did Drug Logic use for you?

A. The reports in the SRS were coded using Costart. The reports in AERS were coded using MedDRA. There is a mapping that maps all the reports the Costart terms to MedDRA terms. So you can go and look the all reports using one dictionary.

Q. Were you aware there was no term for suicide in the Costart dictionary?

A. Prior to?

Q. From '93 to '97 are you aware there was no Costart term for suicide?

report so I would have to go back on line. I looked at everything. I don't necessarily print everything out. You just go through and look.

Q. I think I understand. You looked at it online using Drug Logic's Q Scan?

A. Using the MedDRA dictionary, which is mapped to Costart.

Q. So you are relying on MedDRA's mapping it to Costart to determine if there was a completed suicide, right?

A. That's correct.

Q. And so, if there was no completed suicide code in Costart, then you wouldn't expect to find a completed suicide being mapped to MedDRA?

MR. BARNES: Objection.

A. Theoretically, yes, that would be maybe an issue.

Q. Why would it be an issue?

A. If what you are saying is correct, then it's something that needs to be considered.

Q. Why would it need to be considered?

A. Why?

Q. Why? I want to know why it's important for you to know how many -- why would it need to be considered?

MR. BARNES: Objection.

A. I know there were some issues in the readings about suicidal and terminology about, with a label, but that I was not working on. So mapping them, I'm not going to put an opinion there.

Q. You think it would be important to know, in letting the readers see a PRR of zero, as to whether there was in fact a term for completed suicide in the Costart dictionary that could actually even be mapped to MedDRA?

A. If that's the case, and there are no terms then, yes, that would be important.

Q. Did you ever take any steps personally to determine whether that was in fact the case?

A. I have to go back to my, to look and see what the number of events were. I didn't unfortunately put it in the report.

Q. Where do you have that information, the number of events?

A. How many suicides in each year?

Q. Yes. Where are you keeping it? As we sit here today, where is it? There is a deposition notice that says bring everything you have. So where is it?

A. I mean I looked at it on line from the

A. Well, if there's no suicides, then there would be no suicides. There is both the observed and expected would be zero.

Q. Zero. That would mean that you don't have, and this is all into the hypothetical, of course, that you would have to confirm there were in fact no terms for completed suicide. Now assuming that is the case --

MR. BARNES: Or no mapping.

Q. Or no mapping of the terms to MedDRA. If that's in fact the case, then your PRR is wrong from '93 through '97?

A. It's not wrong. There are none in either source.

Q. I hear you. You're saying it's not on the data, it's not in the data so you are not factually wrong. Because there are no completed suicide terms that you were able to see --

A. If that's the case, absolutely.

Q. But it may have been because there simply wasn't a definition term for it?

MR. BARNES: Objection.

Q. Right? And just to be clear. There would have been no suicides in the background either, correct, assuming that this hypothetical is true,

that there in fact was no Costart term for suicide or there was no mapping of completed suicide to MedDRA, your background would also be zero?

MR. BARNES: Objection.

A. If that's the case, there would be none in either, if there was no term.

Q. So you basically say here zero over zero. From a percentage, from a mathematical equation are we looking at zero over zero?

MR. BARNES: Objection.

A. Yes, but mathematically it has to be one over one.

Q. No. It's zero over zero it should be undefined?

A. Undefined.

Q. If I am right, and there is no completed suicide in Costart, and there is no mapping from Costart to MedDRA for a completed suicide term, then this should really be undefined not zero for that time period we are discussing, right?

A. Well --

Q. You can't zero over zero. You have undefined.

A. Undefined over, divided by undefined would be one. They are identical. So theoretically --

Q. So you think --

A. In the entire database I think there's a problem looking at suicides in AERS.

Q. Accutane, SSRI's, basically notariety bias, those are your issues now in terms of whether to start at that '97. Any other reason?

A. Whether to look at PRR at all even. Whether it's even a valid assessment is a very important scientific question to discuss.

Q. Now are you going to consider it? What are you going to do now as the expert in this case?

A. I stand by my opinion that AERS analysis provides no evidence of an association or a signal or even a hint that Neurontin is associated or even would generate the hypothesis that Neurontin may be associated with suicide.

Q. Would it essentially be your position that a PRR would not be of utility anymore, if in fact this hypothetical was true regarding the lack of a completed suicide term. Because you don't know how to account for the SSRI issue or the Accutane issue or the notariety bias. Would you basically now throw out a PRR?

A. What I'm saying is, the AERS database provides no signal of disproportional reporting at

Q. Undefined would be more accurate, isn't that correct? For the layperson you would put undefined?

A. Undefined or there's none. None. In your hypothetical situation. Yes.

Q. Is that the same as saying zero for PRR? To say none, is that the same as saying PRR zero. Is undefined the same as zero?

A. Undefined, from a mathematical standpoint, is not the same as zero.

Q. That's what I want to know. Okay. If you accept my hypothetical, that there were no completed suicide terms in Costart or there was no completed suicide terms to map to MedDRA, would it now be appropriate for you to start a PRR beginning after November '97, when you know in fact that completed suicides actually do get coded in MedDRA? Wouldn't that be a reasonable place to start? This way you can get rid of all the issue here of zero over zero.

A. The problem is, you don't know when this stimulated reporting began and the issues about suicidality in general in the AERS database where it was stimulated reporting because of issues or SSRI's and other drugs, even Accutane is the example you brought up. So there's an issue.

all for suicide and suicide attempt with Gabapentin.

Q. How do you know that, if your analysis would be wrong, because you included a huge denominator in the background. In other words, you included all the reports for all drugs going across all of time, from '93 forward.

You haven't even begun, you haven't done the analysis to take out the vast number of reports in the background. And then reestablished it from '98 forward to see if during this timeframe, '98 through 2003, there would be any signal. How do you know there would be nothing, no hint, if you haven't done that yet?

A. What you are stating, if hypothetically it's an issue, you're still talking about a proportional reporting rate. So the difference is going to be in the drug that you're looking at and it's also going to be in the comparator.

And so, when you're talking about a relative difference, that's one of the reasons we look relative as opposed to absolute, it's moot.

Q. The comparator in your case so far has been to use all drugs, right?

A. That's correct.

Q. You could avoid the SSRI, you could avoid

as to whether this group of drugs would have been an appropriate group to utilize?

A. Since she didn't do the analysis, I didn't bother going to that step.

Q. Did you think to do the analysis yourself against those comparator drugs?

A. No. Why would I? It would have made no sense.

Q. Did you know even the data that was utilized to formulate this information in Dr. Blume's report was even available to you in the first place?

A. I have to go back to the report to see what the source was.

Q. Your report or her report?

A. For her report. I know what I did.

Q. Let me ask you this way. After November 12th or 13th of 2007, did defense counsel provide you with any CD that was purportedly the data that was utilized to render her opinions on PRR?

A. Actually I did see a CD. I believe your colleague put together quite a wealth of analysis that was the basis for that table.

Q. What did you do with that CD, hopefully

to what you actually reviewed about the CD that was provided to you by counsel, which had been provided to the counsel by me or my colleague? What did you do? You said you reviewed it. Tell me exactly what you did to determine that it was either --

A. Put it in my computer. Looked at the names of the files. I took it out of my computer and I put it aside.

Q. Did you do anything to determine whether any of the plots or any of the data -- when I say plots, any of the plots of the graphs that were on the discs, did you do anything to determine whether any of those plots were inaccurate?

A. No, I didn't. I relied on -- I looked Cheryl Blume's report. That's the basis.

Q. Did you do anything to consider whether any of the data was inaccurate or missing?

A. No. I didn't consider it.

Q. Is there a difference in your mind, when you are reaching this conclusion that there is not a hint of evidence in this case, as you said today, is your opinion that there is no evidence, no reliable evidence or no clear evidence? You used these terms interchangeably throughout the report. I just want to know where you stand on that?

not just use it as a coaster?

A. Actually --

Q. What did you do with it?

A. I looked at it and I put it aside.

Q. When did you do that?

A. Sometime in the course of my review of the material -- October-November-December.

Q. That CD is not on your materials relied upon or considered yet you did --

A. I didn't rely or consider it. No.

Q. What is the threshold for consider -- for any of these documents. What do you have to do to make it reach the considered threshold? You looked at it. You reviewed it in some fashion. You put it aside?

A. I looked at it and said this isn't something I'm going to evaluate. It's not relevant to what I'm doing, or it's nonsense, or it's, in some cases they would send me reports that were too clinically or -- and I just put them aside. I thought they came as mistake or just not relevant to the work I was doing.

Q. Well, in this particular case, and in the context of this particular litigation do you have an independent recollection, as you sit here today, as

A. All of the above. There's nothing.

Q. Let's go back to the Avandia document which was marked as an exhibit. Do you have that exhibit in front of you? What number is that number?

A. It's Exhibit 10.

Q. It's your position this is not a PRR at table 7.1, correct?

A. That's correct. There are no PRR's in this table.

Q. Now it indicates there's a proportion of cardiac events over all events by serious outcome year-end product, correct?

A. That's correct.

Q. Can a reader like yourself with your expertise in epidemiology, can you calculate a PRR using any of the numbers in the columns?

A. No, because it's inappropriate, as I said, to compare one drug to another. That would not be a PRR.

Q. What do you believe the purpose is of this chart in this Avandia briefing document? What is a reader supposed to do with the proportion that's given for each drug?

A. I don't know why they put this table in